VII. Conclusion

All issues raised by the Office Action have been addressed. Reexamination, reconsideration and allowance of claims 1, 4-6, 8, 10-13, 17, and 19-25 is requested.

Respectfully submitted,

Date: January 5, 2004

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Response to Office Action and any other documents referred to as enclosed therein are being deposited with the United States Postal Service on this date **January 5, 2004** in an envelope as "Express Mail Post Office to Addressee" Mailing Label number **EV193721354US** addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Susan Bartholomew
Name of person mailing paper

Date: January 5, 2004

Signature of person signing paper

MARKED UP VERSION OF THE CLAIMS

1. (currently amended) A method for treating an endocrine conditiondisorder, the method comprising the step of intracranial administration of a therapeutically effective amount of a botulinum neurotoxin selected from the group consisting of botulinum toxin types A, B, C_1, D, E, and G to the hypothalamus or pituitary of to a patient, thereby treating a symptom of an endocrine conditiondisorder by reducing a secretion of a hypothalamic or pituitary hormone or releasing hormone, wherein the endocrine condition is selected form the group consisting of gametogenesis, menstruation, acromegaly, gigantism, Cushing's disease, hypergonadism and hyperthyroidism.

2. (cancelled).

3. (cancelled).

4. (currently amended) The method of claim 41, wherein the botulinum toxin is botulinum toxin type A.

5. (currently amended) The method of claim 1, wherein the botulinum toxin is administered in an amount of between about 10^{-2} units and about 500 units.

6. The method of claim 1, wherein the symptom treating effect persists for between about 1 month and about 5 years.

7. (cancelled).

8. (currently amended). The method of claim 71, wherein the botulinum neurotoxin is administered to the median eminence region of the hypothalamus.

9. (cancelled).

10. (currently amended). The method of claim 1~~0~~, wherein the botulinum ~~neuro~~toxin is administered to the anterior pituitary.

11. (currently amended). The method of claim 1 wherein the botulinum ~~neuro~~toxin is administered to the posterior pituitary.

12. (original). The method of claim 1, wherein the intracranial administration step comprises the step of implantation of a controlled release botulinum toxin system.

13. (currently amended). A method for treating an endocrine condition~~disorder~~, the method comprising the step of intracranial administration of a therapeutically effective amount of a botulinum toxin type A to the hypothalamus or pituitary of a patient, thereby alleviating a symptom of an endocrine condition~~disorder~~ by reducing a secretion of a hypothalamic or pituitary hormone or releasing hormone, wherein the endocrine condition is selected form the group consisting of gametogenesis, menstruation, acromegaly, gigantism, Cushing's disease, hypergonadism and hyperthyroidism.

14. (cancelled).

15. (cancelled)..

16. (cancelled).

17. (currently amended). A method for treating an endocrine condition~~disorder~~, the method comprising the steps of:

(a) selecting a neurotoxin with hypothalamic releasing hormone suppressant activity:

(b) choosing a hypothalamic target tissue which influences an endocrine disorder; and;

(c) intracranially administering to the target tissue a therapeutically effective amount of the neurotoxin selected, thereby treating the endocrine condition by reducing a secretion of a hypothalamic releasing hormone, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C_1, D, E, and G and wherein the endocrine condition is selected form the group consisting of gametogenesis, menstruation, acromegaly, gigantism, Cushing's disease, hypergonadism and hyperthyroidism.

18. (cancelled).

19. (currently amended). A method for treating hypergonadism, the method comprising the step of *in vivo* local administration of a therapeutically effective amount of a botulinum toxin type A to a cholinergically influenced hypothalamic tissue to a human patient, thereby alleviating a symptom of hypergonadism in the patient by reducing a secretion of hypothalamic hormone or releasing hormone.

20. (currently amended). A contraceptive method comprising the step of intracranial administration to a hypothalamus or pituitary of a patient of a therapeutically effective amount of a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C_1, D, E, and G ~~to a patient~~, thereby reducing a hypothalamic or pituitary ~~n intracranial~~ secretion of a hormone or releasing hormone required for gametogenesis.

21. (original). The method of claim 20, wherein the botulinum toxin is botulinum toxin type A.

22. (currently amended). A method for inhibiting ovulation, the method comprising the step of intracranial administration to a hypothalamus or pituitary

of a patient of a therapeutically effective amount of a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C_1, D, E, and G ~~to a patient~~, thereby reducing a hypothalamic or pituitary ~~n intracranial~~ secretion of a hormone or releasing hormone which influences ovulation.

23. (original). The method of claim 22, wherein the botulinum toxin is botulinum toxin type A.

24 . (currently amended). A method for inhibiting sperm production, the method comprising the step of intracranial administration to a hypothalamus or pituitary of a patient of a therapeutically effective amount of a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C_1, D, E, and G ~~to a patient~~, thereby reducing a~~n~~ hypothalamic or pituitary ~~intracranial~~ secretion of a hormone or releasing which influences sperm production.

25. (original). The method of claim 24, wherein the botulinum toxin is botulinum toxin type A.